

REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-15 and 17-66 are pending in the subject application. Claim 16 was previously canceled.

Claims 57-66 are acknowledged as being allowable by the Examiner.

Claims 1-15, 17-50 and 55-56 stand rejected under 35 U.S.C. §102 and/or 35 U.S.C. §103. Claims 51-54 were objected to as depending from a rejected base claim, however, the Examiner indicated that these claims would be allowable if appropriately re-written in independent form.

Claims 51-53 were written in independent form as suggested by the Examiner.

Claim 54 was amended so that this claim also depends from claim 53 (*i.e.*, claim 54 previously depended only from any of claims 51-52). As this amendment does not require further search and consideration (*i.e.*, claim 53 is an allowed claim), entry of the amendment is respectfully requested.

The amendments to the claims are supported by the originally filed disclosure.

35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 1-5, 7, 9,-15, 17-20, 22-23, 25-26, 28-38, 40-42, 44-45, 47-50 and 55-56 under 35 U.S.C. §102(b) as being anticipated by Cai et al., “Parametrical Modeling Based Multi-Layered Approach for Design and Validation of Catheterization Devices” [hereinafter “Cai”]. Applicants respectfully traverse as discussed below.

Applicants claim, claim 1, a method for designing a medical device for accessing a body cavity or lumen of a patient. Such a method includes providing data relating to a three-dimensional geometric model of the cavity or lumen to a system that comprises a knowledge base which system performs an analysis using the provided data and obtaining a recommendation from the system based on the analysis, the recommendation relating to the geometry of a device for placement into the cavity or lumen.

As the title of the paper referred herein as Cai implies, this is a methodology paper focusing on parametrical based modeling. Parametrical modeling essentially means representing the geometrical shape of the catheter device using parameters. It is kind of typical in computer aided design (CAD) software packages. As is typical in CAD, one can select a primitive shape (*e.g.*, a long straight cylinder or ring) to start off from, and then changes the parameters defining the cylinder, for example the radius. The collection of shape is like a shape library. In this paper, the shape library was restricted so as to be a collection of curve shapes. As is also typical in CAD, a designer could draw a curve shape based on information from the container (*e.g.*, vessel). This is what was called "model-based catheter design" in the paper. Instead of drawing the

curve shape freely, one may start off with a shape already in place via simulation; this is what was called "navigation-based catheter design". While the vessel appears to be implemented as file system; it is nevertheless, at most a database system.

As is provided in the subject application (see page 7 thereof); as used in the subject application, a "knowledge base " is a data structure comprising facts and rules relating to a subject. As is also provided in the subject application (see page 7 thereof); as used in the subject application, "obtaining a recommendation from a system comprising a knowledge base relating to the geometry of a device" refers to obtaining an output from a system in the form of a volumetric dataset. Preferably, the data in the data set exists in a "virtual" coordinate space, which accurately reflects real-world dimensions of at least a segment of the device, at least with respect to scale, if not actual dimensions.

Applicants also would note that there is an inherent significant difference between knowledge base systems and database systems. A database system, such as that being described in Cai is a store and retrieval type of system, where information is stored in the database and where needed specific data can be retrieved by the database. In contrast, a knowledge base system is capable of making inferences; hence there is a need for both facts and rules. Thus, while a knowledge base system may include a database to carry out its functions it also necessarily includes more functionality than a database system.

In addition, Cai makes numerous references in the discussion in the article to CathWorks and Cai also indicates that CathWorks is a parametrical modeling based multi-layered approach

for catheter device design. As is known to those skilled in the art, CathWorks is a CAD integrated tool kit for feature-based interventional device designing, presenting and validating. CathWorks can be used to prototype or design catheters and CathWorks can be used to verify these designed catheters using a FEM based computerized simulation. Also, a comprehensive database is developed with CathWorks to support a multimedia presentation of catheter devices. In this regard, Applicants would note that an article entitled Catheter Design, Validation and Presentation Using CathWorks was previously submitted by Applicants along with the Response dated December 2, 2004.

While CathWorks was developed using simulation technology, this simulation technology is being used after the catheter is designed to verify the design concept. This is complete different from the claimed invention, where the knowledge base system analyzes the provided data and develops and outputs a recommendation that relates to the geometry of a device for placement into the cavity or lumen. In other words, the system of the present invention provides a recommendation directed to the design of the device that the user then proceeds to use in regards to the design process which is inherently different from that described in Cai and CathWorks.

Also, CathWorks is intended to be a plug-in to, or integrated into, a conventional CAD system such as for example, SolidWorks. CathWorks emphasizes the application of feature based method and parametrical modeling based multi-layer approach that is taken in relatively conventional CAD techniques.

In sum, Cai does not describe, teach nor suggest the methodology as set forth in claim 1, where data of the geometry of the cavity or lumen is provided to a system including a knowledge base and which system develops a recommendation relating to the geometry of a medical device that is to be placed in the body cavity or lumen, which recommendation flows from the analysis of the provided data.

It is respectfully submitted that the foregoing remarks distinguishing claim 1 from Cai also applies to at least distinguish the system of claim 29 and the software suite of claim 49 from the materials embodied in Cai. Applicants also would note that as to claims 29 and 49, that Cai does not describe, teach or suggest the design bases knowledge base as described therein.

As provided in the subject application (see page 7 thereof); as used in the subject application, a "knowledge base " is a data structure comprising facts and rules relating to a subject; for example, a "device shape knowledge base" is a data structure comprising facts relating to geometries for each of a plurality of segments of one or more medical devices and rules for relating these geometries to the geometry of at least a portion of a body cavity or lumen.

As also provided in the subject application (see page 7 thereof); as used in the subject application, a "rule" in a knowledge base refers to a statement associated with a certainty factor. Rules are generally established by interviewing human experts or by obtaining data from databases or other knowledge bases.

Further and as described in the subject application, a system such as that of claim 29, includes a program for applying the rules of one or more knowledge bases to data provided to, or

stored within the knowledge base(s), thereby enabling the knowledge base(s) to be queried and to grow. In more particular preferred embodiments, it also is described that such a system includes an inference engine that enables the system to manipulate input data from a user to arrive at one or more possible answers to a question by a user (*e.g.*, the recommendation of the geometry of the device). In further embodiments, such a system can included a cache or dynamic memory for storing the current state of any active rule along with facts relating to premises on which the rule is based.

The foregoing is not described, taught or suggested anywhere in the materials in Cai. The disclosure in Cai does not present any ideas or concepts in a form whereby one skilled in the art could appreciate the scope of what is being described or so as to enable one skilled in the art to practice the claimed invention or what is alleged to be disclosed therein (*i.e.*, no enabling disclosure).

It also is respectfully submitted that there also is no teaching, suggestion or motivation offered in Cai for modifying the methodology and system disclosed therein so as to yield the method and systems claimed by Applicants.

Each of claims 2-5, 7, 9,-15, 17-20, 22-23, 25-26, 28, 30-38, 40-42, 44-45, 47-48, 50 and 55-56 depend respectfully from one of claims 1, 29 or 49. As such at least because of the dependency from base claim that is believed to be allowable, each of claims 2-5, 7, 9,-15, 17-20, 22-23, 25-26, 28, 30-38, 40-42, 44-45, 47-48, 50 and 55-56 is considered to be allowable.

As to the teachings and disclosures of CathWorks being embedded in the grounds for rejection based on Cai, Applicants would draw the Examiner's attention to the grounds provided for the rejection of claims 55-56. As to this rejection, the Office Action refers to the disclosures in page 34, col. 1 of Cai. It should be noted that the discussion contained in the first paragraph in col. 1 on page 34 (*i.e.*, the only paragraph in col. 1 that is not in the "Conclusions" clearly relates to CathWorks.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the above-identified claims are not anticipated by the Cai et al. article.

It is respectfully submitted that for the foregoing reasons, claims 1-5, 7, 9,-15, 17-20, 22-23, 25-26, 28-38, 40-42, 44-45, 47-50 and 55-56 are patentable over the cited reference and thus, satisfy the requirements of 35 U.S.C. §102(b). As such, these claims, including the claims dependent therefrom are allowable.

35 U.S.C. §103 REJECTIONS

Claims 6, 8, 21, 24, 27, 39, 43 and 46 stand rejected under 35 U.S.C. § 103 as being unpatentable over Cai in view of one of James Anderson, et al.; Virtual Reality in Interventional Radiology [“Anderson] for claims 6 and 39; in view of DiGioia et al; [USP 6,205,411, DiGioia”] for claims 8, 21, 24 and 43; or Ulug [USP 4,918,620] for claims 27 and 46 as provided on pages 7-9 of the above-referenced Office Action. Applicants respectfully traverse that these claims would be obvious and thus unpatentable in view of the identified cited combinations of references.

As indicated in the discussion above regarding the cited Cai et al. article, Cai does not disclose, teach nor suggest the inventions set forth in either claim 1 or claim 29 of the present invention. As also indicated above, the Cai article also does not teach, suggest nor offer any motivation for modifying the methods and systems disclosed therein so as to yield the method or systems as set forth in either of claim 1 or claim 29.

Each of claims 6, 8, 21, 24, 27, 39, 43 and 46 depend respectfully from one of claims 1 or 29. As such at least because of the dependency from base claim that is believed to be allowable, each of claims 6, 8, 21, 24, 27, 39, 43 and 46 are considered to be allowable.

Applicants also would note that each of the secondary references is being cited as providing a teaching or a suggestion directed to the specific feature of the dependent claim being rejected. As such, it is respectfully submitted that the combination of the primary or principal reference, with any of the cited secondary references fails to overcome the deficiencies in the

primary reference provided in the §102 discussion provided above. Applicants would note that the foregoing remarks distinguishing claims 6, 8, 21, 24, 27, 39, 43 and 46 shall not be construed as an admission that these claims are not separately patentable over the cited combination of references.

As to the secondary references Applicants make the following observations. Anderson DiGioia and Ulug do not contain or imply any "intelligence" - capability of making inference. DiGioia describes a computer assisted surgery planner and intra-operative guidance system. Ulug is directed to generic computer software architecture and operating system but includes no discussion not teaching as to a medical diagnosis expert system nor a system for design medical devices.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation.

Furthermore, and as provided in MPEP 2143.02, a prior art reference can be combined or modified to reject claims as obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Additionally, it also has

been held that if the proposed modification or combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. Further, and as provided in MPEP-2143, the teaching or suggestion to make the claimed combination and the reasonable suggestion of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As can be seen from the forgoing discussion regarding the disclosures of the cited references, there is no reasonable expectation of success provided in the reference(s).

It is respectfully submitted that for the foregoing reasons, claims 6, 8, 21, 24, 27, 39, 43 and 46 are patentable over the cited reference(s) and thus, satisfy the requirements of 35 U.S.C. §103. As such, these claims are allowable.

CLAIMS 51-54

In the above-referenced Office Action, claims 51-54 were objected to as being dependent upon a rejected base claim. It also was provided in the above-referenced Office Action, however, that these claims would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claim(s).

Claim(s) 51-53 were re-written in the foregoing amendment so as to be in independent form and to include all the limitations of the base claim (claim 1) there being no intervening claim(s). Accordingly, claims 51-53 are considered to be in allowable form.

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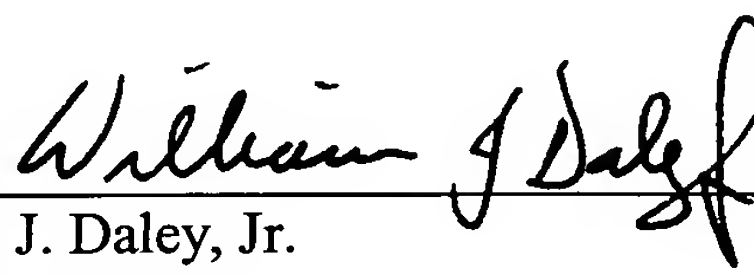
As to claim 54, this claim was not re-written in independent form as suggested by the Examiner. Applicants however, reserve the right to later amend the subject application so as to present this claim in independent form or to add an independent claim that contains the limitations of this claim. Applicants would note that claim 54 was amended so that it now depends from claims 51-53.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Because the total number of claims and/or the total number of independent claims post amendment now exceed the highest number previously paid for, a check is enclosed herewith for the required additional fees. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
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